K092159

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

### 1. Submitter's Information: 21 CFR 807.92(a)(1)

MEDISON CO., LTD. 1003, Daechi-dong, Gangnam-gu, Seoul 135-280, Korea

JUL 2 8 2009

#### **Contact Person:**

Mr. Kyung-Am, Shim Regulatory Affairs Manager

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Data Prepared: February 29, 2008

### 2. Name of the device:

#### Common/Usual Name:

Diagnostic Ultrasound System and Accessories

### Proprietary Name:

ACCUVIX V20 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

#### 3. Identification of the predicate or legally marketed device:

K080800, ACCUVIX V20 Diagnostic Ultrasound System K052911, ACCUVIX XQ Diagnostic Ultrasound System

### 4. Device Description:

The ACCUVIX V20 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, M mode, Color Doppler mode, Power Doppler mode, PW Spectral Doppler, CW Spectral Doppler mode, and Tissue Doppler Image mode on the LCD display. It also provides the 3D/4D imaging mode using the 3D/4D probe in the Mechanical scan mode.

The ACCUVIX V20 has real time acoustic output display with two basic indices, a

mechanical index and a thermal index, which are both automatically displayed. The system also provides for the measurement of anatomical structures and for analysis packages that provide information used for clinical diagnostic purposes by competent health care professionals.

The ACCUVIX V20 has been designed to meet the following product safety standards:

- UL 60601-1. Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993-1, Biocompatibility

#### 5. Intended Uses:

The ACCUVIX V20 system and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include:

General, abdomen, obstetrics, gynecology, vascular, extremity, pediatric, cardiac, breast, urology, neonatal cephalic, trans-esophageal, and etc.

#### 6. Technological Characteristics:

The ACCUVIX V20 is substantially equivalent to the ACCUVIX V20 Diagnostic Ultrasound System, cleared via K080800, and the ACCUVIX XQ Diagnostic Ultrasound System, cleared via K052911. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Medison Co., Ltd. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25<sup>th</sup> Street NW BUFFALO MN 55313

JUL 2 8 2009

Re: K092159

Trade/Device Name: ACCUVIX V20 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasound pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 15, 2009 Received: July 16, 2009

### Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACCUVIX V20 Diagnostic Ultrasound System, as described in your premarket notification:

### Transducer Model Number

<u>3D2-6ET</u>	<u>C3-7IM</u>
<u>3D4-8ET</u>	<u>C4-9/10ED</u>
3D4-9ES	<u>EC4-9IS</u>
3D5-9EK	ER4-9/10ED
<u>V2-6</u>	<u>EV4-9/10ED</u>
<u>V4-8</u>	<u>L4-7EL</u>
<u>V5-9</u>	<u>L5-12/50EP</u>
<u>V6-12</u>	<u>L5-13IS</u>
<u>C2-5EL</u>	<u>L7-16IS</u>
<u>C2-6IC</u>	<u>LF5-12</u>

MPT4-7	P3-8CA
<u>P2-4AC</u>	CW 2.0
P2-4BA	<u>CW 4.0</u>
P3-5AC	•

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

If you have any questions regarding the content of this letter, please contact Robert Ochs at (240) 276-3666.

Sincerely yours,

Janine M. Morris

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

### Section 4.3 INDICATIONS FOR USE

### DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.:

Device Name:

ACCUVIX V20 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use		Mode of Operation (*includes simultaneous B-mode)								
Clinical Application General Specific			B M PWD CWD Color Combined* C							
General (Track I only)	(Tracks I & III)		IV1	PWD	CWD	Doppler*	(Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal (See Note 3)	P	P	P	P	P	Note 1	Notes 2, 7, 8		
	Abdominal	P	P	P	P	Ρ.	Note 1	Notes 2, 7, 8		
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)							<u>.</u>		
Fetal Imaging	Laparoscopic									
& Other	Pediatric	Ρ.	P	P	P	P	Note 1	Note 2,4,5,6,7,8,9		
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2,5,6,8,9		
	Neonatal Cephalic	N	N	N		N	Note 1			
ě	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7		
	Trans-rectal	P	P	P		P	Note 1	Note 2, 3, 7, 8		
	Trans-vaginal	P	P	P		P	Note I	Note 2, 3, 7, 8		
	Trans-urethral			l						
	Trans-esoph. (non-Cardiac)	Ń	N	N	N	N				
	Musculo-skel. (Convent.)	P	P	P		P	Note I	Note 2,5,6,8,9		
	Musculo-skel. (Superfic.)	P	P	P		P	Note I	Note 2,5,6,8,9		
	Intra-luminal						1			
	Other (spec.)		T							
<del></del>	Cardiac Adult	Р	P	P	Р	P	Note 1	Note 4, 7		
Cardiac	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7		
	Trans-esophageal (Cardiac)	N	N	N	N	N				
	Other (spec.)									
Peripheral	Peripheral vessel	P	P	P	P	P	Note 1	Note 5, 6, 9		
Vessel	Other (spec.)									

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name:

3D2-6ET for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	· · · · · · · · · · · · · · · · · · ·									
General	inical Application	- n	Mode of Operation (*includes simultaneous B-mode)  B M PWD CWD Color Combined* Other							
(Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Doppler*	Combined* (Spec.)	(Spec.)		
	Ophthalmic					Doppier	(Spec.)	(Spec.)		
Ophthalmic	•	·								
	Fetal (See Note 3)	P	P	P		P	Note I	Notes 2, 7, 8		
· ·	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8		
	Intra-operative (See Note 6)	<u> </u>								
	Intra-operative (Neuro.)	<b>L</b>	<u> </u>							
Fetal Imaging	Laparoscopic									
& Other	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8		
	Small Organ (See Note 5)	I					_			
	Neonatal Cephalic									
1	Adult Cephalic									
	Trans-rectal									
•	Trans-vaginal									
	Trans-urethral							<u> </u>		
	Trans-esoph. (non-Cardiac)							,		
	Musculo-skel. (Convent.)	1		-						
	Musculo-skel. (Superfic.)			1						
	Intra-luminal	1		<u> </u>						
	Other (spec.)									
	Cardiac Adult						·	· ·		
Cardiac	Cardiac Pediatric									
	Trans-esophageal (Cardiac)	1		T .		1				
	Other (spec.)	1								
Peripheral	Peripheral vessel	$\Box$			, i					
Vessel	Other (spec.)									

N= new indication; P= previously cleared under K080800; E= added under Appendix E

#### **Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

K092159

510(k) No.:

Device Name:

3D4-8ET for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation (*includes simultaneous B-mode)							
Generat (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
<u>.                                      </u>	Fetal (See Note 3)	P	P	P		Р	Note 1	Notes 2, 7, 8		
	Abdominal	P	P	P		P	Note I	Notes 2, 7, 8		
	Intra-operative (See Note 6)							, , , , , , , , , , , , , , , , , , , ,		
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic				-					
& Other	Pediatric	P	P	P		P	Note I	Notes 2, 7, 8		
	Small Organ (See Note 5)									
	Neonatal Cephalic									
•	Adult Cephalic									
	Trans-rectal					· · · · · · · · · · · · · · · · · · ·				
	Trans-vaginal									
	Trans-urethral	1			-					
	Trans-esoph. (non-Cardiac)									
	Musculo-skel. (Convent.)	1								
	Musculo-skel. (Superfic.)									
•	Intra-luminal									
	Other (spec.)		_							
	Cardiac Adult									
Cardiac	Cardiac Pediatric			-						
	Trans-esophageal (Cardiac)	, ·						.'		
·	Other (spec.)									
Peripheral	Peripheral vessel							<del> </del>		
Vessel	Other (spec.)	Π	1							

N= new indication; P= previously cleared under K080800; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE	.)
Prescription Use (Per 21 CFR 801.109)	
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(Division \$ign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

K092159

510(k) No.:

Device Name:

3D4-9ES for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	: Diagnostic ultrasou	nd 11	magi					ian body as follows:		
Clinical Application			Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal (See Note 3)									
	Abdominal									
	Intra-operative (See Note 6)		<u>.</u>							
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic									
& Other	Pediatric	1								
	Small Organ (See Note 5)						-			
	Neonatal Cephalic									
	Adult Cephalic	I	l							
-	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 8		
	Trans-vaginal	P	P	P		Р.	Note I	Notes 2, 7. 8		
	Trans-urethral									
	Trans-esoph. (non-Cardiac)	ļ								
٠,	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)					·				
	Intra-luminal									
	Other (spec.)					<u> </u>				
	Cardiac Adult									
Cardiac	Cardiac Pediatric							·		
	Trans-esophageal (Cardiac)							'		
	Other (spec.)									
Peripheral	Peripheral vessel							\		
Vessel	Other (spec.)				]	<u> </u>	1			

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

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Prescripti	ion Úse (Per 21 CFR 801.109)
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(Division Sign-Off)	
Division of Reproduc	otivo Abdominal

Division of Reproductive, Abdominal and

Radiological Devices Ko92159

510(k) No.:

Device Name:

3D5-9EK for use with ACCUVIX V20

Intended lise Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
-	Fetal (See Note 3) Abdominal	_								
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)			ļ .	· · · · · · · · · · · · · · · · · · ·					
Fetal Imaging	Laparoscopic Pediatric									
& Other		<b> </b>	-			1				
	Small Organ (See Note 5) Neonatal Cephalic	$\vdash$								
	Adult Cephalic	<del>                                     </del>			` "	···				
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 8		
	Trans-vaginal	P	P	P		P	Note I	Notes 2, 7. 8		
	Trans-urethral									
	Trans-esoph. (non-Cardiac)				-					
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)	L								
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric	<u> </u>					<u></u>			
	Trans-esophageal (Cardiac)	<u> </u>								
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)			1		-				

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of (	DRH, Office of Device Evaluation (ODE
Pres	cription Use (Per 21 CFR 801.109)
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(Division Sign	-Off)
Division of Re	productive, Abdominal and
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Radiological Devices

510(k) No.:

Device Name:

V2-6 for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use Cl	Clinical Application Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)	N	N	N		N	Note 1	Notes 2, 7, 8
	Abdominal .	N	N	N		N	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N	N	N		N	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)			\				
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral			1				
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal	$\Box$						
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office	of Device Evaluation (ODE)
Prescription Vse (Po	er 2/ CFR 801.109)
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(Division Sign-Off)	
Division of Reproduct	ive, Abdominal a <b>nd</b>
Radiological Devices	4000, TA
510(k) Number	1012151

510(k) No.:

Device Name:

V4-8 for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the numan body as follows:									
Cl	inical Application	Mode of Operation (*includes simultaneous B-mode)							
General	Specific	В	М	PWD	CWD	Color	Combined*	Other	
(Track I only)	(Tracks I & III)		<u></u>			Doppler*	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic	!	ļ 						
	Fetal (See Note 3)	N	N	N		N	Note 1	Notes 2, 7, 8	
	Abdominal	N	N	N		N_	Note 1	Notes 2, 7, 8	
	Intra-operative (See Note 6)								
	Intra-operative (Neuro.)				-				
Fetal Imaging	Laparoscopic								
& Other	Pediatric	N	N	N		N	Note I	Notes 2, 7, 8	
•	Small Organ (See Note 5)								
	Neonatal Cephalic								
	Adult Cephalic	I							
	Trans-rectal		l						
	Trans-vaginal		<u> </u>						
	Trans-urethral	L.							
	Trans-esoph. (non-Cardiac)		1						
1	Musculo-skel. (Convent.)			ļ					
	-Musculo-skel. (Superfic.)								
	Intra-luminal								
	Other (spec.)	<u> </u>							
	Cardiac Adult							<u>.</u>	
Cardiac	Cardiac Pediatric	乚	<u> </u>	ļ		1			
	Trans-esophageal (Cardiac)			<u> </u>		<u> </u>		·	
	Other (spec.)					·			
Peripheral	Peripheral vessel						·.		
Vessel	Other (spec.)	<u> </u>		1				]	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

510(k) No.:

Device Name: V5-9 for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CI	inical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic						•			
	Fetal (See Note 3) Abdominal									
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)		·							
Fetal Imaging	Laparoscopic									
& Other	Pediatric									
	Small Organ (See Note 5)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	N.	N	N		N	Note 1	Notes 2, 7, 8		
•	Trans-vaginal	N	N	N		N	Note 1	Notes 2, 7. 8		
	Trans-urethral									
•	Trans-esoph. (non-Cardiac)	T						•		
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)			Ì						
•	Intra-luminal									
	Other (spec.)					·	• .			
	Cardiac Adult		<u> </u>							
Cardiac	Cardiac Pediatric	1	<u> </u>	<u> </u>		·		···-		
	Trans-esophageal (Cardiac)	·						. <u>-</u>		
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)	l		<u> </u>						

N= new indication; P= previously cleared by FDA; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Concurrence of CDRH, Office of Device Evaluation (ODE)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Prescription 1	Use (Per 21 CFR 801.109
let	1 m
(Division Sign-Qff)	
Division of Reproductiv	ve, Abdominal and
Radiological Devices	K192159
510/k) Number	V01~121

510(k) No.:

Device Name: V6-1

V6-12 for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

· C	linical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal (See Note 3) Abdominal									
	Intra-operative (See Note 6)							-		
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic									
& Other	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 9		
	Small Organ (See Note 5)	N	N	N		N	Note 1	Note 2, 5, 6, 9		
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal					,				
	Trans-vaginal		ļ							
	Trans-urethral					·				
	Trans-esoph. (non-Cardiac)	1								
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 9		
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 9		
	Intra-luminal	1						,		
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
•	Trans-esophageal (Cardiac)			-						
<u> </u>	Other (spec.)			·						
Peripheral	Peripheral vessel	N	N	N		N	Note 1	Note 5, 6, 9		
Vessel	Other (spec.)				<u></u>	<u> </u>	L l	· •		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurren	ice of CDRH,	Office	of Device	<b>Evaluation</b>	(ODE)
	Prescription				, .

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

510(k) No.:

C2-5EL for use with ACCUVIX V20 Device Name:

С	linical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8		
	Abdominal	P	P	P	,	P	Note I	Notes 2, 7, 8		
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic	T								
& Other	Pediatric	P	P	.P		P	Note I	Notes 2, 7, 8		
	Small Organ (See Note 5)	1	1							
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Cardiac)			T	-					
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal					[				
	Other (spec.)	-								
• .	Cardiac Adult			-						
Cardiac	Cardiac Pediatric									
	Trans-esophageal (Cardiac)									
	Other (spec.)							•		
Peripheral	Peripheral vessel									
Vessel	Other (spec.)				,		]			

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CI	RH, Off	jee (	of De	evice	Eval	uation	(ODE)
Prescri	tion Use	(Per	21 C	TR 8	01.1	ng)	

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name:

C2-6IC for use with ACCUVIX V20

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Intended Use: Mode of Operation (\*includes simultaneous R-mode)

С	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	linical Application Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8	
	Abdominal	P	P	P		P	Note I	Notes 2, 7, 8	
	Intra-operative (See Note 6)							·	
	Intra-operative (Neuro.)					,			
Fetal Imaging	Laparoscopic								
& Other	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8	
	Small Organ (See Note 5)								
	Neonatal Cephalic						<u> </u>		
	Adult Cephalic			•					
	Trans-rectal							· · · · · · · · · · · · · · · · · · ·	
	Trans-vaginal								
	Trans-urethral	``I							
	Trans-esoph. (non-Cardiac)							,	
	Musculo-skel. (Convent.)			Ì					
	Musculo-skel. (Superfic.)						<u> </u>		
	Intra-luminal						<u></u>		
	Other (spec.)		ļ						
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esophageal (Cardiac)								
	Other (spec.)					,			
Peripheral	Peripheral vessel					·			
Vessel	Other (spec.)					<u> </u>			

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (	(ODE)
Prescription Use (Per 21 CFR 801.109)	

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

510(k) No.:

Device Name:

C3-7IM for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	linical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8		
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8		
	Intra-operative (See Note 6)		l							
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic					·				
& Other	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8		
	Small Organ (See Note 5)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal		Ţ							
	Trans-urethral							·		
	Trans-esoph. (non-Cardiac)	•								
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)	•								
- 1	Cardiac Adult									
Cardiac	Cardiac Pediatric						-			
	Trans-esophageal (Cardiac)					,				
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)									

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

711

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) No.:

Device Name:

C4-9/10ED for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use		1 1111	agi				ides simultaneous	
	linical Application	В	137	PWD	CWD	Color	Combined*	Other
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	·	Doppler*	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		<u> </u>	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
·	Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic			•				
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)	P	P	P		P	Note 1	Notes 2, 7, 8
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 2, 7, 8
. !	Adult Cephalic					·		
	Trans-rectal						·	
	Trans-vaginal				ļ			
•	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)					-		
	Musculo-skel. (Superfic.)							
	Intra-luminal		П				-	
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	Note 1	Notes 2, 7, 8
Vessel	Other (spec.)		Γ					

N= new indication; P= previously cleared under K063580; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note'3: Includes infertility monitoring of follicle development

Note 4: Color M-mode.

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

510(k) No.:

Device Name: E

EC4-9IS for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	·	na 1111	agu					
	linical Application	<del>  _</del>	13.71				es simultaneous Combined*	Other
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
<del></del>	Fetal (See Note 3)							
•	Abdominal				1			
	Intra-operative (See Note 6)							-
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	1.						
& Other	Pediatric							
•	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral					· ·		
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric				· 1			
	Trans-esophageal (Cardiac)							
	Other (spec.)							<u> </u>
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared under K080800; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development.

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign\0ff)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name: ER

ER4-9/10ED for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	<u> </u>	Mode of Operation (*includes simultaneous B-mode)										
	linical Application	<del> </del>	T 7 7 1									
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)											
	Abdominal	`										
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic							×				
& Other	Pediatric											
	Small Organ (See Note 5)											
	Neonatal Cephalic											
•	Adult Cephalic						·					
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 8				
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 8				
	Trans-urethral				`							
	Trans-esoph. (non-Cardiac)											
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superfic.)											
	Intra-luminal											
•	Other (spec.)			-								
	Cardiac Adult	Ì										
Cardiac	Cardiac Pediatric											
	Trans-esophageal (Cardiac)											
•	Other (spec.)											
Peripheral	Peripheral vessel											
Vessel	Other (spec.)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

### **Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

C	Concurrence of CDRH, Office of Device Evaluation (ODE	)
	Prescription Use (Por 21 CFR 801.109)	
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Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name: EV4-9/10ED for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application		Mode of Operation (*includes simultaneous B-mode)										
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)					
Ophthalmic	Ophthalmic				_								
	Fetal (See Note 3)	·	· .	<u>'</u>									
	Abdominal	<u> </u>	<u> </u>										
	Intra-operative (See Note 6)												
	Intra-operative (Neuro.)												
Fetal Imaging	Laparoscopic												
& Other	Pediatric												
	Small Organ (See Note 5)												
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal	N	N	N		. N	Note I	Note 2, 7, 8					
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 8					
	Trans-urethral												
	Trans-esoph. (non-Cardiac)												
	Musculo-skel. (Convent.)												
	Musculo-skel. (Superfic.)												
	Intra-luminal												
	Other (spec.)												
	Cardiac Adult	T											
Cardiac	Cardiac Pediatric												
	Trans-esophageal (Cardiac)												
	Other (spec.)						·						
Peripheral	Peripheral vessel												
Vessel	Other (spec.)							·					

N= new indication; P= previously cleared by FDA; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name: La

L4-7EL for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	: Diagnostic ultrasou	nd imaging or fluid flow analysis of the human body as follows:										
C	linical Application			Mod	e of Oper	ation (*includ	les simultaneous					
General	Specific	В	М	PWD	CWD	Color	Combined*	Other				
(Track I only)	(Tracks I & III)					Doppler*	(Spec.)	(Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)											
	Abdominal											
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 9				
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 9				
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal					·						
	Trans-urethral											
	Trans-esoph. (non-Cardiac)											
ļ	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 9				
	Musculo-skel. (Superfic.)	P	P	P		P	Note I	Note 2, 5, 6, 9				
	Intra-luminal											
	Other (spec.)											
	Cardiac Adult					1						
Cardiac	Cardiac Pediatric					·						
	Trans-esophageal (Cardiac)		<u> </u>	<u> </u>	ļ		·					
	Other (spec.)					,						
Peripheral	Peripheral vessel	P	P	P		P	Note 1	Note 5, 6, 9				
Vessel	Other (spec.)											

N= new indication; P= previously cleared under K080800; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign 10ff)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name: L5-12/50EP for us

L5-12/50EP for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	linical Application	Mode of Operation (*includes simultaneous B-mode)										
General	Specific	В	M	PWD	CWD	Color	Combined*	Other				
(Track I only)	(Tracks I & III)					Doppler*	(Spec.)	(Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)											
	Abdominal							•				
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)						c					
Fetal Imaging	Laparoscopic					•						
& Other	Pediatric	P	P	P		P	Note I	Note 2, 5, 6, 7, 9				
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9				
	Neonatal Cephalic											
	Adult Cephalic					• .						
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral							*				
_	Trans-esoph. (non-Cardiac)						-					
•	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9				
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9				
	Intra-luminal											
	Other (spec.)				l							
	Cardiac Adult											
Cardiac	Cardiac Pediatric					, ,						
	Trans-esophageal (Cardiac)											
	Other (spec.)											
Peripheral	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9				
Vessel	Other (spec.)											

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name:

L5-13IS for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

intended Use C	linical Application	Mode of Operation (*includes simultaneous B-mode)										
General	Specific	В	М	PWD	CWD	Color	Combined*	Other				
(Track I only)	(Tracks I & III)	<u>L.</u>		<u>_</u> .		Doppler*	(Spec.)	(Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)											
	Abdominal	<u> </u>	<u> </u>									
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatric	Р	P	P		. P	Note 1	Note 2, 5, 6, 7, 9				
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9				
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral	1										
	Trans-esoph. (non-Cardiac)							• ' ' '				
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9				
	Musculo-skel. (Superfic.)	P	P	P		P	Note I	Note 2, 5, 6, 7, 9				
	Intra-luminal				,							
	Other (spec.)	1		<u> </u>								
	Cardiac Adult							•				
Cardiac	Cardiac Pediatric	1						· ·				
	Trans-esophageal (Cardiac)											
	Other (spec.)				1							
Peripheral	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9				
Vessel	Other (spec.)											

N= new indication; P= previously cleared under K080800; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name:

L7-16IS for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

ntended Use	: Diagnostic ultrasour	Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic	•									
	Fetal (See Note 3) Abdominal										
	Intra-operative (See Note 6) Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic										
& Other	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 9			
	Small Organ (See Note 5)	P	P	P		Р.	Note I	Note 2, 5, 6, 9			
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal						·				
	Trans-urethral							·			
	Trans-esoph. (non-Cardiac)						•				
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 9			
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 9			
	Intra-luminal										
	Other (spec.)										
Cardiac	Cardiac Adult Cardiac Pediatric										
	Trans-esophageal (Cardiac)			1							
	Other (spec.)		l				* -				
Peripheral Vessel	Peripheral vessel Other (spec.)	P	P	P		P	Note 1	Note 2, 5, 6, 9			

N= new indication; P= previously cleared under K080800; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Fer 21 CFR 801.109)

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(Division Sigh Off)
Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name:

LF5-12 for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use	na im	d imaging or fluid flow analysis of the human body as follows:										
	linical Application	ــــــ	Mode of Operation (*includes simultaneous B-mode)  B M PWD CWD Color Combined* Other									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)											
	Abdominal											
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatric	N	N	N		N .	Note 1	Note 2, 5, 6, 7, 9				
	Small Organ (See Note 5)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9				
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal							• .				
	Trans-vaginal											
	Trans-urethral							,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
	Trans-esoph. (non-Cardiac)											
	Musculo-skel. (Convent.)	N	N·	N		N	Note 1	Note 2, 5, 6, 7, 9				
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9				
	Intra-luminal		[									
	Other (spec.)											
	Cardiac Adult	<u> </u>										
Cardiac	Cardiac Pediatric							. "				
	Trans-esophageal (Cardiac)											
	Other (spec.)											
Peripheral	Peripheral vessel	N	N	Ň		N	Note 1	Note 2, 5, 6, 7, 9				
Vessel	Other (spec.)			]	<u> </u>							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device E	
Prescription Use (Per 21 CFR 80)	1.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

K092159

510(k) No.:

Device Name:

MPT4-7 for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

С	linical Application	<u></u>	Mode of Operation (*includes simultaneous B-mode)										
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)					
Ophthalmic	Ophthalmic												
	Fetal (See Note 3)			•									
	Abdominal												
	Intra-operative (See Note 6)			,				,					
	Intra-operative (Neuro.)												
Fetal Imaging	Laparoscopic												
& Other	Pediatric												
	Small Organ (See Note 5)				T								
	Neonatal Cephalic												
	Adult Cephalic	1											
	Trans-rectal												
•	Trans-vaginal												
	Trans-urethral												
	Trans-esoph. (non-Cardiac)	N	N	Ņ		N	Note 1	Note 7, 8					
	Musculo-skel. (Convent.)		1										
	Musculo-skél. (Superfic.)												
•	Intra-luminal												
	Other (spec.)												
	Cardiac Adult						·						
Cardiac	Cardiac Pediatric												
	Trans-esophageal (Cardiac)	N	N	N		N	Note 1	Note 7, 8					
	Other (spec.)		'										
Peripheral	Peripheral vessel				· ·	`							
Vessel	Other (spec.)					• .							

N= new indication; P= previously cleared under K052911; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

510(k) No.:

**Device Name:** 

P2-4AC for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use		na im:	agıng										
C	linical Application		Mode of Operation (*includes simultaneous B-mode)										
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)					
Ophthalmic	Ophthalmic						,						
	Fetal (See Note 3)						·						
	Abdominal	P	P	P	P	Ρ.	Note I	Note 4, 7					
	Intra-operative (See Note 6)												
	Intra-operative (Neuro.)												
Fetal Imaging	Laparoscopic												
& Other	Pediatric												
	Small Organ (See Note 5)												
	Neonatal Cephalic		Τ										
	Adult Cephalic	· P	P	P	P	P	Note 1	Note 4, 7					
	Trans-rectal												
	Trans-vaginal			l									
	Trans-urethral							·					
	Trans-esoph. (non-Cardiac)				<u> </u>			-					
•	Musculo-skel. (Convent.)												
	Musculo-skel. (Superfic.)				L								
	Intra-luminal			l			ļ						
-	Other (spec.)												
•	Cardiac Adult	P	P	P	P	P	Note I	Note 4, 7					
Cardiac	Cardiac Pediatric	P	P	P	P	P	. Note I	Note 4, 7					
	Trans-esophageal (Cardiac)												
	Other (spec.)												
Peripheral	Peripheral vessel												
Vessel	Other (spec.)	<u> </u>											

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (OI	JE)
Prescription Use (Per 21 CFR 801.109)	

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) No.:

Device Name:

P2-4BA for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application			Mode	of Opera	tion (*includ	es simultaneous	B-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)				l			
	Abdominal	N	N	N	N	N	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)				,			
Fetal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	N	Ň	N	N	N	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal				,			
•	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal		Î					
	Other (spec.)							
	Cardiac Adult	N.	N	N	N	N	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)				ļ			•
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, C					ODE
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

(092/59

510(k) No.:

Device Name:

P3-5AC for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use		na mil	aging					
	linical Application	D.	1 16		of Opera		es simultaneous I Combined*	3-mode) Other
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	(Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic				İ			
	Fetal (See Note 3)							
	Abdominal	P	P	P	P	P	Note I	Note 4, 7
	Intra-operative (See Note 6)						]	
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric		Ī					
	Small Organ (See Note 5)							
•	Neonatal Cephalic				·			
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)						- 1	
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	P	P	P	Note I	Note 4, 7
	Trans-esophageal (Cardiac)							*.
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)	1 .						

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CER 801.109)

(Division Sigh-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

510(k) No.:

Device Name:

P3-8CA for use with ACCUVIX V20

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use		na im:	aging					
	Clinical Application						es simultaneous	
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	¢wd	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							·
	Abdominal	N	N	N	N	N	Note 1	Note 4, 7
•	Intra-operative (See Note 6)							
•	Intra-operative (Neuro.)							· · · · · · · · · · · · · · · · · · ·
Fetal Imaging	Laparoscopic							
& Other	Pediatric		Ĭ <u>_</u> _					
•	Small Organ (See Note 5)							·
	Neonatal Cephalic							
ė.	Adult Cephalic	N	N	N	N	И	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
•	Musculo-skel. (Superfic.)				<u> </u>	·	<u>                                     </u>	
	Intra-luminal							
•	Other (spec.)			l	<u> </u>			
	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	. N	N	N	N	N	Note i	Note 4, 7
	Trans-esophageal (Cardiac)							
·	Other (spec.)		<u> </u>		1			
Peripheral	Peripheral vessel							
Vessel	Other (spec.)		1	<u></u>		<u> </u>		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

#### **Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

510(k) No.:

Device Name:

CW 2.0 for use with ACCUVIX V20

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Intended Hee

Intended Use	inical Application	Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3) Abdominal Intra-operative (See Note 6) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (See Note 5) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal				P			
	Trans-urethral Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)							
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (Cardiac) Other (spec.)				P P			
Peripheral Vessel	Peripheral vessel Other (spec.)				P			

N= new indication; P= previously cleared under K080800; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (OD Prescription Usq (Per 21 CFR 801.109)	E)
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Division of Reproductive, Abdominal and	

Radiological Devices 510(k) Number

510(k) No.:

Device Name:

CW 4.0 for use with ACCUVIX V20

postic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use		nd ii	nagi									
	linical Application	<u> </u>	Mode of Operation (*includes simultaneous B-mode)  B M PWD CWD Color Combined* Other									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	(Spec.)				
Ophthalmic	Ophthalmic						·					
	Fetal (See Note 3)	L	<u> </u>									
	Abdominal		<u> </u>	<u> </u>								
	Intra-operative (See Note 6)				<u> </u>	<u> </u>						
	Intra-operative (Neuro.)					<u> </u>	<u>.                                    </u>					
Fetal Imaging	Laparoscopic				<u> </u>	<u> </u>						
& Other	Pediatric				P		·					
	Small Organ (See Note 5)											
	Neonatal Cephalic						<u> </u>					
	Adult Cephalic		Ţ <u></u>	]	P							
•	Trans-rectal											
	Trans-vaginal											
•	Trans-urethral		l									
•	Trans-esoph. (non-Cardiac)						<u> </u>					
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superfic.)											
	Intra-luminal											
	Other (spec.)											
<del></del>	Cardiac Adult	1			P							
Cardiac	Cardiac Pediatric				Р							
	Trans-esophageal (Cardiac)											
•	Other (spec.)							·				
Peripheral	Peripheral vessel				P			•				
Vessel	Other (spec.)					,						

N= new indication; P= previously cleared under K080800; E= added under Appendix E

### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
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510(k) Number \_\_\_\_